

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)	
COMPOUNDING PHARMACY, INC.)	MDL No. 2419
PRODUCTS LIABILITY LITIGATION)	Dkt. No. 1:13-md-2419-RWZ
_____)	
)	
This Document Relates to:)	
)	
Suits Identified in Exhibit A)	
_____)	

**The Tennessee Defendants' Reply to the
Plaintiffs' Steering Committee's Fed. R. Civ. P. 56(d) Response to
the Tennessee Defendants' Motion for Summary Judgment**

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively "the Tennessee Defendants") file this Reply to the Plaintiffs' Steering Committee's ("PSC") Fed. R. Civ. P. 56(d) Response to the Tennessee Defendants' Motion for Summary Judgment [Dkt. 948].

Background

In a “health care liability action” where expert testimony is required by § 29-26-115¹, a plaintiff must file a certificate of good faith with the complaint.² If the certificate of good faith is not filed with the complaint, the complaint “shall be dismissed.”³

Thirty-three (33) lawsuits in this MDL were filed against the Tennessee Defendants without a certificate of good faith accompanying the original complaint. The Defendants moved for summary judgment on these complaints pursuant to Tenn. Code Ann. § 29-26-122.⁴ Because the Defendants submitted affidavits to establish material facts, the Defendants filed the dispositive motion as a motion for summary judgment.⁵

The Plaintiffs do not dispute that the complaints were filed without the required certificate, but instead filed a response pursuant to Fed. R. Civ. P. 56(d) requesting “full discovery” prior to the Court ruling on the Motion.⁶

The Plaintiffs’ response ignores the clear, applicable statutory mandate, and focuses on immaterial issues. The Plaintiffs’ request should be denied, and the Court should rule on the Defendants’ Motion for Summary Judgment in these 33 cases.⁷

¹ Tenn. Code Ann. § 29-26-115 requires that a plaintiff in a health care liability action prove with expert testimony (1) the standard of care applicable to the defendant, (2) that the defendant breached the standard of care, and (3) that the breach proximately caused the injury. TENN. CODE ANN. § 29-26-116(a). *Each* element must be established by expert testimony, including causation. *Payne v. Caldwell*, 796 S.W.2d 142, 143 (Tenn. 1990).

² TENN. CODE ANN. § 29-26-122(a).

³ *Id.*

⁴ Dkt. 774.

⁵ Dkts. 774-78.

⁶ PSC’s Fed. R. Civ. P. 56(d) Resp. to Mot. for Summ. J., at 16 [Dkt. 948] [*Hereinafter* “PSC’s Resp.”].

⁷ Attached as Exhibit A is a list identifying the cases in which the Plaintiffs failed to file the required certificate of good faith with the original complaint, which are the subject of the instant Motion for Summary Judgment. The list has been updated since the filing of the Motion to identify additional cases in which the Plaintiff filed a certificate of good faith with an amended complaint filed after the Motion.

Introduction

In 2011, the Tennessee Legislature ended plaintiffs' former practice of disguising professional medical negligence actions as other causes of action to avoid the requirements of the Health Care Liability Act.⁸ In unambiguous language, the Legislature made clear that "any civil action," "regardless of the theory of liability on which the action is based," is a "health care liability action" if it "alleg[es] that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person."⁹

The Plaintiffs in these 33 lawsuits proceeded as if the 2011 amendment to the Act never happened and ignored the applicable provisions as if they were irrelevant. The Plaintiffs' argument that the provisions do not apply to their Complaints requires the Court to find that either (1) the Legislature did not mean what it said when defining a health care liability action or (2) that the Legislature simply forgot about the existence of the product liability statute in choosing not to carve out an exception in the Health Care Liability Act for product liability claims.¹⁰ The Plaintiffs read an exception into the Act that plainly does not exist.

⁸ See comments of (sponsoring) Senator Norris, May 12, 2011, responding to questions about intent of bill: "It is advantageous in the minds of some plaintiffs to keep it out from under the health care provider statutes, make a cause of action look like something it isn't at its core, so you spend most of your time at the outset trying to define what the cause of action is. We're hopeful that this statute will obviate some of that and reduce some of that time and expense," available at http://tnga.granicus.com/MediaPlayer.php?view_id=196&clip_id=4266&meta_id=81904, (discussion beginning at 1:04:00). The bill passed in the Senate that day, was passed in the House on May 20, 2011, and signed by the governor June 16, 2011.

⁹ TENN. CODE ANN. § 29-26-101(a)(1).

¹⁰ Of course, "courts must 'presume that the legislature says in a statute what it means and means in a statute what it says there.' Accordingly, courts must construe a statute as it is written." *Gleaves v. Checker Cab Transit Corp., Inc.*, 15 S.W.3d 799, 803 (Tenn. 2000) (internal citations omitted). Likewise, the Court must assume that the Legislature knew of its prior enactments and the state of the law when passing a statute. *Brundage v. Cumberland Cnty.*, 357 S.W.3d 361, 365 (Tenn. 2011).

In their response, the Plaintiffs take the Court through a convoluted and roundabout discussion of product liability and civil conspiracy but skip the actual issue presented in the Defendants' Motion: Have the Plaintiffs alleged claims for injury related to the provision of health care services? If the answer is "yes," the Plaintiffs can allege any cause of action they wish in their Complaints, but the requirements of the Health Care Liability Act still apply, including the certificate of good faith requirement.

Putting aside the Plaintiffs' hyperbolic commentary regarding the Defendants' Motion¹¹, the Defendants base their position squarely on the plain language of the Act. Frankly, the Court need consider little (if anything) else. On the other hand, to adopt the Plaintiffs' position would require the Court to cast entirely aside the clear statutory language establishing the intent of the Act.

The Plaintiffs' request for discovery on immaterial issues should be denied, and the Court should grant the Defendants' Motion for Summary Judgment.

Standard of Review

A party seeking to invoke Rule 56(d) must generally show (1) good cause for not obtaining the sought-after facts sooner, (2) a plausible basis for its belief that those facts exist, and (3) that it will discover those facts in a reasonable amount of time.¹² Additionally, important here, the non-movant must demonstrate that the discoverable facts are genuine *and material* to the pending motion for summary judgment.¹³ The non-

¹¹ For example: "The [Defendants'] motion is deliberately opaque presumably because the Tennessee Defendants are attempting to confuse the Court about the nature and requirements of Tennessee law." PSC's Resp. at 6. "The Tennessee Defendants obfuscate that fact by claiming that the Plaintiffs assert causes of action under both the Tennessee Products Liability Act and the THLA, citing the Master Complaint as the basis for this assertion. This is very misleading." PSC's Resp. at 7.

¹² *Chung v. Studentcity.com, Inc.*, No. 10-10943-RWZ (D. Mass. 2013) (citing *Morrissey v. Boston Five Cents Sav. Bank*, 54 F.3d 27, 35 (1st Cir. 1995)).

¹³ *Licari v. Ferruzzi*, 22 F.3d 344, 350 (1st Cir. 1994) (approving denial of then-numbered Rule 56(f) motion where the evidence sought was not the type that would render the claims viable).

movant must also set out the *specific* facts that it seeks to establish as necessary to rebut the motion.¹⁴ Identification of *any* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. The dispute must be of a *genuine* issue of *material* fact.¹⁵

Law and Argument

I. The dispositive legal issue raised in the Tennessee Defendants' Motion for Summary Judgment is whether the Plaintiffs' claims are "related to" the provision of health care services and are, thus, governed by the Tennessee Health Care Liability Act, including the certificate of good faith requirement.

The Plaintiffs attempt to redirect the Court from the actual issue at hand by suggesting that the Court must determine whether the Tennessee Defendants are "sellers" under Tennessee's Product Liability Act¹⁶ to rule on the pending Motion for Summary Judgment.¹⁷ While creative, this characterization of the issue before the Court is a classic red herring.

The Defendants agree that the issue of whether the Defendant health care providers engaged in a "sale" when administering epidural steroid injections to patients is an issue of law relevant to determining whether the Defendants can be held liable under a product liability theory.¹⁸ It is, however, immaterial to resolution of this Motion.

The dispositive issue here is whether the Plaintiffs allege injury related to the provision of health care. If so, the action is a "health care liability action," and each

¹⁴ *Rivera-Torres v. Rey-Hernandez*, 502 F.3d 7, 12 (1st Cir. 2007).

¹⁵ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

¹⁶ TENN. CODE ANN. § 29-28-101, *et seq.*

¹⁷ PSC's Resp. at 5-6.

¹⁸ As explained in the Tennessee Defendants' pending "Global" Motion to Dismiss, 23 of 25 states that have considered this question, in addition to respected tort commentators, agree that health care providers are not engaged in the business of selling the products used incidental to the provision of health care services. Dkt. 772 at 31-44.

Plaintiff *must* file a certificate of good faith with the original complaint, “regardless of the theory of liability on which the action is based.”¹⁹

A. The Health Care Liability Act governs claims against health care providers “related to” the provision of health care services, “regardless of the theory of liability on which the action is based.”

The Court need go no further than the statutory definition of a “health care liability action” to swiftly resolve those threshold issues.

Tenn. Code Ann. § 29-26-122 requires a plaintiff to file a certificate of good faith with any complaint alleging a health care liability action where expert proof is required by Tenn. Code. Ann. § 29-26-115. Section -115 requires expert proof of a violation of the acceptable standard of professional practice in all health care liability actions except for those that fit two limited exceptions not applicable here.²⁰

Therefore, the operative question before the Court in resolving the Defendants’ Motion for Summary is whether the Plaintiffs’ claims are health care liability actions as defined by the Act.

“Health care liability action” means any civil action...alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.²¹

Plainly, the Plaintiffs allege injury “related to the provision of...health care services,” meaning their claims are health care liability actions. The Plaintiffs’ product liability claim

¹⁹ TENN. CODE. ANN. §§ 29-26-122, 29-26-101(a)(1).

²⁰ “Expert testimony is unnecessary when the subject matter of the [health care liability] claim lies within the common knowledge of lay persons” (e.g., a sponge is left in the patient). *Deuel v. Surgical Clinic, PLLC*, 2010 WL 3237297, at *9 (Tenn. Ct. App. Aug. 16, 2010). Relatedly, in narrow circumstances, plaintiffs in a health care liability action are entitled to a rebuttable presumption of negligence where the plaintiff proves “the instrumentality causing injury was in the defendant’s (or defendants’) exclusive control and that the accident or injury was one which ordinarily doesn’t occur in the absence of negligence.” *Id.* at *11 (quoting Tenn. Code Ann. § 29-26-115(c)). These two narrow exceptions do not require expert proof or the related certificate of good faith. But, neither exception applies here.

²¹ TENN. CODE ANN. § 29-26-101(a)(1).

is simply another “theory of liability on which the [Plaintiffs’ health care liability action] is based.”²²

However, the Plaintiffs apparently contend that the Tennessee legislature did not actually mean “any civil action...regardless of the theory of liability on which the action is based,” despite the plain language of the statute.²³ The Plaintiffs contend that a product liability claim against a health care provider for injury related to the provision of health care is not a health care liability action. But, the Plaintiffs cite no legal authority for this proposition (because no such authority exists).

B. Additional discovery is unnecessary to resolve the Defendants’ Motion for Summary Judgment.

Importantly, for the purpose of the Plaintiffs’ request for discovery under Fed. R. Civ. P. 56(d), the interaction between Tennessee’s Health Care Liability Act and Tennessee’s Product Liability Act is a legal issue the Court can resolve without further discovery.

The affidavits of Drs. Culclasure and Lister, which converted the instant motion from a Rule 12(b)(6) motion to dismiss into a Rule 56 motion for summary judgment, definitively establish that the Defendants are health care providers as defined and governed by the Act.^{24 25} The Plaintiffs neither dispute nor request additional discovery on this issue.

Likewise, the Plaintiffs do not dispute their failure to comply with the certificate of good faith requirement in filing their original complaints. None of the discovery sought

²² *Id.*

²³ *Id.*

²⁴ TENN. CODE ANN. § 29-26-101(a)(2).

²⁵ See Culclasure Aff., ¶¶ 2-4, 8, 10-14; Lister Aff., ¶¶ 2-4, 6-9.

by the Plaintiffs will excuse that failure. The Court should deny the Plaintiffs' request for additional discovery.

II. The discovery sought by the Plaintiffs is not material to resolution of the Tennessee Defendants' Motion for Summary Judgment.

The Plaintiffs' response fails to identify the *specific* facts it expects to discover that will create a genuine issue of *material* fact.²⁶ The Plaintiffs generally request "further discovery" but fail to identify the specific facts they expect to discover that will support denial of the Motion.²⁷ The general categories of information upon which the Plaintiffs seek discovery are utterly immaterial to the resolution of the Defendants' Motion for Summary Judgment. The discovery sought has no bearing on whether the Plaintiffs' claims are subject to the certificate of good faith requirement.

A. The determination of whether the Tennessee Defendants are "sellers" is immaterial to whether the Plaintiffs were required to comply with the certificate of good faith requirement in filing their original complaints.

Discovery regarding whether the Defendants "sold" medication to the Plaintiffs is unnecessary to resolve the Tennessee Defendants' Motion for Summary Judgment. The seller-service provider distinction is not even mentioned in the Motion. That particular ground for dismissal of the Plaintiffs' product liability claim is raised as an alternative ground for dismissal in the Tennessee Defendants' "Global" Motion to Dismiss.²⁸

Without rehashing the entire brief here, the Plaintiffs' product liability claim fails as a matter of law for two reasons.

²⁶ *Rivera-Torres*, 502 F.3d at 12; *Licari*, 22 F.3d at 350.

²⁷ Gastel Decl. ¶¶ 11, 13, 15, 17; *Rivera-Torres*, 502 F.3d at 12; *Licari*, 22 F.3d at 350.

²⁸ Dkts. 771-72.

First, product liability without fault is inconsistent with the burden of proof requirements set forth in the statute governing the Plaintiffs' Complaints, the Health Care Liability Act.²⁹

Second *and in the alternative*, based on analogous Tennessee case law and the overwhelming majority of case law in other jurisdictions, health care providers are service providers, not “sellers” engaged in the business of selling the products used incidental to the provision of health care services. The Court will only reach this alternative argument *if it finds that the Health Care Liability Act does not apply to the Plaintiffs' Complaints*. In that case, the certificate of good faith requirement would also not apply, rendering the Defendants' Motion for Summary Judgment moot. For purposes of these 33 cases, the Court need not reach these more substantive arguments on the viability of the product liability claim. Therefore, discovery regarding whether the Defendants “sold” the contaminated medication to patients is not material to the instant Motion for Summary Judgment.³⁰

The other discovery sought by the Plaintiffs goes to *the merits* of the product liability claim, namely, whether the product was contaminated when it left the control of the Defendants and caused injury to the Plaintiffs. However, the Motion for Summary Judgment does not seek summary judgment on the merits of the claim. It seeks summary judgment based on the Plaintiffs' failure to file the required certificate of good faith. Accordingly, this evidence is immaterial to the Motion.

²⁹ The Health Care Liability Act requires expert proof of the acceptable standard of professional practice and forbids the presumption of negligence. TENN. CODE ANN. § 29-26-115. Strict product liability is inconsistent with both provisions.

³⁰ In his declaration, Mr. Gastel suggests that discovery is necessary to obtain patient billing statements because “these documents have not been produced in this litigation.” Gastel Decl. ¶ 11. This is untrue. HIPAA requires health care providers, including the Tennessee Defendants, to provide medical and billing records to patients upon request. The Tennessee Defendants produced that information to dozens of Plaintiffs in response to HIPAA-compliant requests, both prior to and during this litigation.

In fact, the Defendants could theoretically concede, for the limited purpose of this Motion for Summary Judgment, that they sold contaminated medication to patients causing the alleged injuries, without affecting resolution of the Motion for Summary Judgment in any way. It simply has no bearing on whether the Plaintiffs' claims are "related to the provision of health care services" and subject to the certificate of good faith requirement. The Plaintiffs have not (and cannot) demonstrate otherwise.

B. Evidence of the Tennessee Defendants' alleged participation in a civil conspiracy is immaterial to whether the Plaintiffs were required to file a certificate of good faith with their original complaints.

Next, the Plaintiffs claim they need discovery to support their alleged civil conspiracy claim. The Plaintiffs assert that "[f]urther discovery is needed to fully understand [the Defendants'] role in actively participating with NECC in violating Massachusetts law."³¹ Yet again, the Plaintiffs neglect to give any explanation as to why that information is necessary *to adjudicate the instant Motion for Summary Judgment*.

The reason for this glaring omission is obvious: the discovery sought is immaterial to the Motion. The merit, or lack thereof, of the civil conspiracy claims does not affect whether the Plaintiffs were required to file a certificate of good faith with their original complaints.

Again, the Defendants could theoretically concede, for the limited purpose of this Motion for Summary Judgment, that they participated in the alleged civil conspiracy, and it would not affect the Court's adjudication of the Motion. The merit of the civil conspiracy claim bears no relationship to whether the Plaintiffs' claims are "related to the provision of health care services" subject to the certificate of good faith requirement. Any argument to the contrary is baseless.

³¹ Gastel Decl. ¶¶ 15, 17.

C. Evidence of the Tennessee Defendants' compliance with the applicable standard of care is immaterial to resolution of the Motion for Summary Judgment, which hinges on whether the Complaints allege injury related to the provision of health care.

First of all, the Plaintiffs fail to properly support the request for discovery regarding the Tennessee Defendants' alleged liability under the Health Care Liability Act with a supporting affidavit or declaration as required by Fed. R. Civ. P. 56(d). The Declaration of Benjamin Gastel completely ignores this point. Accordingly, the Court should deny the Plaintiffs' request for discovery on this issue on that basis alone.³²

Additionally, evidence of the Tennessee Defendants' liability under the Health Care Liability Act is irrelevant to resolution of the Motion for Summary Judgment. The Motion does not seek summary judgment *on the merits* of the Plaintiffs' claims under the Act. It seeks summary judgment on the Plaintiffs' failure to comply with the Act's mandatory, threshold certificate of good faith requirement.³³

Notwithstanding these inadequacies in the Plaintiffs' response, the Tennessee Defendants contemporaneously file an Amended Statement of Undisputed Material Facts, specifically withdrawing from the Statement of Undisputed Material Facts the paragraphs regarding Dr. Culclasure and Dr. Lister's compliance with the applicable standard of care. This amendment nullifies the Plaintiffs' specious claim that they need discovery on this issue prior to resolution of the Motion.

³² Fed. R. Civ. P. 56(d); *Morrissey v. Boston Five Cents Sav. Bank*, 54 F.3d 27, 35 (1st Cir. 1995) (denying request for additional discovery where affidavit did not address the allegedly disputed facts).

³³ The cases cited by the Plaintiffs pertain to motions for summary judgment on the merits, not on the failure to file a certificate of good faith, and are, therefore, inapplicable.

Conclusion

The Tennessee Defendants hereby request that the Court:

(1) Deny the Plaintiffs' Fed. R. Civ. P. 56(d) request for "full discovery" on matters immaterial to resolution of the Tennessee Defendants' Motion for Summary Judgment, and

(2) Grant the Motion for Summary Judgment in the 33 suits identified in Exhibit A.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

C.J. Gideon, Jr.³⁴

Chris J. Tardio³⁴

Alan S. Bean³⁵

Matthew H. Cline³⁴

John-Mark Zini³⁴

315 Deaderick Street, Suite

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (515) 254-0459

chris@gideoncooper.com

Attorneys for the Tennessee Defendants

³⁴ Admitted pursuant to MDL Order No. 1.

³⁵ Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 14th day of March, 2014.

/s/ Chris J. Tardio
Chris J. Tardio